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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/774,751	Applicant(s) GRYCHOWSKI ET AL.
	Examiner NIHIR PATEL	Art Unit 3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02.08.2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-14,24-30 and 32-35 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-14,24-30 and 32-35 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Allowable Subject Matter

1. The indicated allowability of claims **1, 3-14, 24-27, 29, 32 and 33** is withdrawn in view of the newly discovered reference(s). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 1, 8-14, 29 and 33-35** are rejected under 35 U.S.C. 102(e) as being anticipated by Brooker et al. (US 6,805,118).

4. **As to claim 1**, Brooker teaches an apparatus that comprises a chamber **20** (see **figure 4**) housing defining an interior space and comprising an input end (see **figure 4**) and an output end (see **figure 4**); a one way inhalation valve positioned upstream of the interior space, the one way inhalation valve **16** (see **figure 4; column 4 lines 35-45**) operative to permit a flow of gases into the interior space of the chamber housing; a first inhalation conduit **4** (see **figure 4; column 3 lines 50-60**) communicating with the output end of the chamber, the first inhalation conduit comprising an inlet communicating with the output end of the chamber housing and an outlet adapted to transmit medication to the patient, wherein the inlet and outlet are axially aligned with the output end of the holding chamber; a second inhalation conduit communicating with the

input end of the chamber housing, wherein the one way inhalation valve is located in the second inhalation conduit, the second inhalation conduit comprising an oxygen intake line communicating with the one way inhalation valve (see **figure 4; the combination of the connector 14 and the elbow connector 15 define the second inhalation conduit wherein the one way valve 16 is located**); an exhaust conduit 5 (see **figure 4; column 4 lines 10-20**) communicating with the first inhalation conduit at a location positioned between the inlet and the outlet of the first inhalation conduit (see **figure 2**); and a one-way exhaust valve 6 (see **figure 2; column 3 lines 54-60**) located in the exhaust conduit, the one way exhaust valve adapted to prevent a backflow of gas from the exhaust conduit into the first inhalation conduit (see **figure 2**).

5. **As to claim 8**, Brooker teaches an apparatus wherein the first inhalation conduit comprises an endotracheal tube (see **column 2 lines 45-55**).

6. **As to claim 9**, Brooker teaches an apparatus wherein the fist inhalation conduit comprises a mask (see **column 2 lines 45-55**).

7. **As to claim 10**, Brooker teaches an apparatus that comprises an adaptor 3 connected to the output end of the chamber housing and comprising a first portion defining at least a portion of the first inhalation conduit and a second portion defining at least a portion of the exhaust conduit, wherein the one way valve exhaust valve is positioned in the second portion of the adaptor, and further comprising an exhaust line connected to the second portion and defining at least a portion of the exhaust conduit (see **figure 2; column 3 lines 54-65**).

8. **As to claim 11**, Brooker teaches an apparatus that comprises a chamber 20 (see **figure 4**) housing defining an interior space and comprising an input end (see **figure 4**) and an output end

(see figure 4); a one way inhalation valve positioned upstream of the interior space, the one way inhalation valve 16 (see figure 4; column 4 lines 35-45) positioned upstream of the interior space, the one way inhalation valve operative to permit a flow of gases into the interior space of the housing; an inhalation conduit 4 (see figure 4; column 3 lines 54-60) communicating with the output end of the chamber, the inhalation conduit adapted to transmit medication to the patient; an exhaust conduit 5 communicating with the inhalation conduit (see figure 2; column 3 lines 54-60); a one way exhaust valve 6 (see figure 2; column 3 lines 54-60) located in the exhaust conduit, the one way exhaust valve adapted to prevent a backflow of gas from the exhaust conduit into the inhalation conduit; an adaptor 3 (see column 3 lines 5-60) connected to the output end of the chamber and comprising a first portion defining at least a portion of the inhalation conduit and a second portion defining at least a portion of the inhalation conduit and a second portion defining at least a portion of the exhaust conduit, wherein the one way exhaust valve is positioned in the second portion of the adaptor, and further comprising an exhaust line connected to the second portion and defining at least a portion of the exhaust conduit, wherein the first portion defines a first passageway having a first and second channel and wherein the second portion comprises a second passageway, and wherein the adaptor further defines a third passageway communicating between the first passageway and second passageways, wherein the one way exhaust valve is disposed in the second passageway (see figures 2 and 4).

9. As to claim 12, Brooker teaches an apparatus that further comprises a connector member connecting the second portion and the exhaust line (see figure 2).

10. **As to claim 13**, Brooker teaches an apparatus wherein the first channel has a first cross sectional area and the second channel has a second cross sectional area, wherein the second cross sectional area is greater than the first cross sectional area (**see figures 2 and 4**).

11. **As to claim 14**, Brooker teaches an apparatus that further comprises a shoulder formed at the interface of the first and second channels, and wherein the third passageway communicates with the second channel at the shoulder (**see figures 2 and 4**).

12. **As to claim 29**, Brooker teaches an apparatus wherein the second inhalation conduit is isolated from and does not communicate with ambient air (**see figures 2 and 4**).

13. **As to claim 33**, Brooker teaches an apparatus that comprises a chamber 20 (**see figure 4**) housing defining an interior space and comprising an input end (**see figure 4**) and an output end (**see figure 4**); a one way inhalation valve positioned upstream of the interior space, the one way inhalation valve 16 (**see figure 4; column 4 lines 35-45**) positioned upstream of the interior space, the one way inhalation valve operative to permit a flow of gases into the interior space of the chamber housing; a first inhalation conduit 4 (**see figure 4; column 3 lines 50-60**) communicating with the output end of the chamber, the first inhalation conduit comprising an inlet communicating with the output end of the chamber housing and an outlet adapted to transmit medication to the patient, wherein a flow path between the interior of the chamber housing and the outlet of the first inhalation conduit through the output end of the chamber housing is free of any valve structure (**see figures 2 and 4**); a second inhalation conduit communicating with the input end of the chamber housing, wherein the one-way inhalation vale is located in the second inhalation conduit, the second inhalation conduit comprising an oxygen intake line communicating with the one way inhalation valve (**see figures 2 and 4**); an exhaust

conduit **5** (see figures **2** and **4**; column **3** lines **54-60**) communicating with the first inhalation conduit; a one way exhaust valve **6** (see figure **2**; column **3** lines **54-60**) located in the exhaust conduit, the one way exhaust valve adapted to prevent a backflow of gas from the exhaust conduit into the first inhalation conduit (see figures **2** and **4**).

14. **As to claim 34**, Brooker teaches an apparatus that further comprises a WYE connector connecting the second inhalation conduit and the exhalation conduit (see figure **2** and column **3** lines **54-60**).

15. **As to claim 35**, Brooker teaches an apparatus wherein the oxygen intake line and the exhalation conduit are connected to a ventilator (see figure **4**).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. **Claims 24-27 and 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker et al. (US 6,805,118).

19. **As to claims 24-27 and 32**, Brooker substantially discloses method steps of transmitting oxygen from a ventilator through a holding chamber and inhalation conduit 4 to a patient during an inhalation sequence of breathing cycle; introducing the medication into the holding chamber 20; preventing a substantial transmission of an exhaust gas into the holding chamber during an exhalation sequence of the breathing cycle; transmitting a substantial portion of the exhaust gas into an exhaust conduit 5 during the exhalation sequence; and preventing a substantial transmission of the exhaust gas from the exhaust conduit into the inhalation conduit during subsequent inhalation sequences of subsequent breathing cycles; and transmitting the substantial portion of the exhaust gas from exhaust conduit to the ventilator during the exhalation sequence (see column 3 lines 54-60 and column 4).

The method steps would have been obvious because they would have resulted from the use of the device of claim 1; of Brooker.

Claim Rejections - 35 USC § 103

20. **Claims 3-7, 28 and 30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker et al. (US 6,805,118) in view of Walstrom et al. (US 5,178,138).

21. **As to claims 3, 4, 28 and 30**, Brooker substantially discloses an apparatus that comprises a chamber 20 (see figure 4) housing defining an interior space and comprising an input end (see figure 4) and an output end (see figure 4), wherein the interior space has a first cross sectional area defined substantially perpendicular to a longitudinal flow direction adjacent to the input

end; a one way inhalation valve positioned upstream of the interior space, the one way inhalation valve 16 (see figure 4; column 4 lines 35-45) operative to permit a flow of gases into the interior space of the chamber housing; a first inhalation conduit 4 (see figure 4; column 3 lines 50-60) communicating with the output end of the chamber, the first inhalation conduit comprising an inlet communicating with the output end of the chamber housing and an outlet adapted to transmit medication to the patient, wherein the inlet and outlet are axially aligned with the output end of the holding chamber; a second inhalation conduit communicating with the input end of the chamber housing, wherein the one way inhalation valve is located in the second inhalation conduit, the second inhalation conduit comprising an oxygen intake line communicating with the one way inhalation valve (see figure 4; the combination of the connector 14 and the elbow connector 15 define the second inhalation conduit wherein the one way valve 16 is located); an exhaust conduit 5 (see figure 4; column 4 lines 10-20) communicating with the first inhalation conduit at a location positioned between the inlet and the outlet of the first inhalation conduit (see figure 2); and a one-way exhaust valve 6 (see figure 2; column 3 lines 54-60) located in the exhaust conduit, the one way exhaust valve adapted to prevent a backflow of gas from the exhaust conduit into the first inhalation conduit (see figure 2) but does not disclose a pressurized metered dose inhaler within the second conduit downstream of the one way inhalation valve and upstream of the interior space of the chamber housing.

Walstrom teaches an apparatus that does provide pressurized metered dose inhaler within the second conduit downstream of the one way inhalation valve and upstream of the interior space of the chamber housing (see figures 6 and 11). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Brooker's invention by

providing pressurized metered dose inhaler within the second conduit downstream of the one way inhalation valve and upstream of the interior space of the chamber housing as taught by Walstrom in order to obtain the correct amount of the mixture.

22. **As to claims 5,** Brooker substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a one way inhalation valve that comprises a valve member, a valve seat and a blocking member disposed in the second inhalation conduit, wherein the blocking member is spaced downstream from the valve seat, and wherein the valve member is disposed between the blocking member and the valve seat. Walstrom discloses an apparatus that does provide a one way inhalation valve that comprises a valve member, a valve seat and a blocking member disposed in the second inhalation conduit, wherein the blocking member is spaced downstream from the valve seat, and wherein the valve member is disposed between the blocking member and the valve seat (**see figure 6**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Brooker's invention by providing a one way inhalation valve that comprises a valve member, a valve seat and a blocking member disposed in the second inhalation conduit, wherein the blocking member is spaced downstream from the valve seat, and wherein the valve member is disposed between the blocking member and the valve seat as taught by Walstrom in order to have better control of the mixture.

23. **As to claim 6,** Brooker substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a valve member that is a center post valve member connected to the valve seat. Walstrom teaches an apparatus that does provide a valve member that is a center post valve member connected to the valve seat (**see figure 6**). Therefore, it would

have been obvious to one having ordinary skill in the art at the time the invention was made to modify Brooker's invention by providing a valve member that is a center post valve member connected to the valve seat as taught by Walstrom in order to have better control of the mixture.

24. **As to claim 7**, Brooker substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a blocking member that has at least one opening formed therein to permit the flow of gases therethrough. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Brooker's invention by providing a blocking member that has at least one opening formed therein to permit the flow of gases therethrough as taught by Walstrom in order to have better control of the mixture.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772